Application No.: 10/789,312
Filed: February 27, 2004
TC Art Unit: 1644
Confirmation No.: 9773

REMARKS

Claims 18-47 are pending. Claims 1-17 were previously cancelled. Claims 18-21, 25, 31-39, and 46-47 are withdrawn. Claims 22-24, 26-30, and 40-45 are currently under examination. Claims 22, 23, and 26 have been amended in order to incorporate material from, or eliminate dependency on, a withdrawn claim. Claims 28 and 29 have been amended to recite an "isolated" host cell, as requested by the Examiner. No new matter has been introduced.

Objection to claims 22-24

Claims 22-24 are objected to as depending upon non-elected claims. The appropriate material from the withdrawn base claims has been incorporated into claims 22 and 23, thereby eliminating dependency on any withdrawn claim and the basis for the objection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 22-30 and 40-45 are rejected as allegedly lacking enablement. The rejection is respectfully traversed.

The Office Action admits at Section 10 that the specification is enabling for the nucleic acid sequence of SEQ ID NO:1 encoding the protein of SEQ ID NO:5 and a method of producing the protein

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of SEQ ID NO:5 using the nucleic acid of SEQ ID NO:1. However, the Office Action states that undue experimentation would be required for an isolated nucleic acid molecule according to claim 22, which encodes the protein of claim 18, and as well for the isolated nucleic acid molecule according to claim 23, which encodes the peptide of claim 21. The Office Action also appears to suggest that the use of "comprising" language for the nucleic acid molecule of claim 24, the vector of claims 26, and the host cell of claim 28 results in a requirement for undue experimentation. Applicants disagree.

Claim 22, as presently amended, recites a nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:5, or conservative amino acid substitutions thereof. First, that the specification enables the use of degenerate nucleotide sequences that encode SEQ ID NO:5 should be non-controversial, as this is completely predictable and established in the case law. Second, conservative amino acid substitutions, which are well understood in the art and entirely predictable, can be introduced into proteins with a high probability of retaining biological activity. Any reasonable uncertainty regarding the retention of biological activity if such substitutions are made has been removed in the present case by the

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requirement for retention of allergen activity. For example, claim 22 states, "wherein said protein is capable of inducing an allergic reaction to latex in a person sensitized to said protein." Third, even though open language is used, the claims require either a nucleotide sequence encoding SEQ ID NO:5 or a biologically active portion thereof. Moreover, the addition of amino acids to either the N-terminus or C-terminus of SEQ ID NO:5 or a biologically active portion thereof still has to satisfy the requirement for preserving allergenic activity, as recited in the claims.

The Office Action discusses publications such as Attwood and Skolnick which emphasize how small changes in amino acid sequence can, occasionally, have an unpredictable effect on biological function for certain proteins. However, these publications attempt to address changes in amino acid sequences in general and not conservative amino acid substitutions as required by Applicants' claims. The usual case for conservative amino acid substitutions or for additions of amino acids to the ends of a sequence with biological activity is that the activity is retained. These modifications have largely predictable effects that are well known in the art, and are not generally unpredictable as the Office Action alleges. Finally, the Examiner

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cannot overlook the requirement stated in the claims that allergenic activity is retained. One assay for determining allergenic activity is disclosed, for example, in Example 5.

Therefore, because the specification teaches how to make and use the full range of nucleic acid molecules covered by the subject claims, the withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 22, 23, 26-30, and 40-45 are rejected as allegedly obvious over Yeang, as evidenced by Arif, and further in view of Villalba and Sowka. The rejection is respectfully traversed.

As a threshold matter, Applicants point out that although the rejection seems intended as an obviousness rejection, the Office Action states at Section 14, first sentence, that the subject claims are "anticipated." This is assumed to be an error, and the rejection, which is based on a combination of several references, will be treated as an obviousness rejection. For the reasons outlined below, none of the references cited could anticipate the subject claims, because none discloses all the limitations of the subject claims.

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The Office Action points out that Yeang teaches an allergenic protein of 42.98 kDa at page 39, first full paragraph. Even if, *arguendo*, that 42.98 kDa protein corresponds to the protein whose amino acid sequence is given by SEQ ID NO:5, the disclosure by Yeang et al. is not enabling. A few features of a 42.98 kDa allergenic protein are provided, such as its mass and the observation of some unspecified level of homology to early nodule-specific protein of soya bean (not "high" homology as stated in the Office Action). Even if the 42.98 kDa protein of Yeang was identical to the present SEQ ID NO:5, Yeang is not enabling because Yeang does not teach how to purify the protein. The Yeang reference merely provides a few hints that the protein of the present invention exists in certain extracts, but does not teach how to make the isolated protein. Furthermore, the mere mention of homology to the soya bean protein does not provide sufficient information to render obvious the presently claimed nucleic acid molecules, because no region of homology, and therefore no relevant sequence information, was disclosed in Yeang.

Arif, which was published after the priority date of the present application, reveals a partial sequence of SEQ ID NO:5. The sequence shown in Fig. 3 of Arif lacks, however, amino acids 1-12 and 404-464 of SEQ ID NO:5, leaving doubt whether the Yeang

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protein is the same as SEQ ID NO:5, or a variant. Even if this partial sequence were enough to convincingly identify the Yeang 42.98 kDa protein as the same as that shown in the present SEQ ID NO:5, Yeang fails to provide an enabling disclosure for the 42.98 kDa protein.

Villalba is cited as teaching the cloning and sequencing of an olive tree allergen, which is unrelated to the latex allergen of the present claims. Sowka is cited as teaching the low concentration of latex allergens, making them attractive targets for recombinant production. Neither Villalba nor Sowka cures the defects of Yeang. None of the cited references, either alone or in combination, teaches the amino acid or nucleotide sequences of the subject claims, or how to make the isolated protein whose amino acid sequence is shown in SEQ ID NO:5.

Therefore, because the cited references, either alone or in combination, fail to teach the limitations of the subject claims, the withdrawal of this rejection is respectfully requested.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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